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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

Elvira L. Gordon and Brian Gordon Plaintiffs, vs. Optumrx, Inc.; Merck & Co., Inc.; Merck Sharp & Dohme Corp.; Northstar RX LLC; and DOES 1 to 50, inclusive, Defendants.	Case No. 8:20-cv-00449 JVS-JDE **FIRST AMENDED COMPLAINT FOR DAMAGES AND INJUNCTION** **1. Violation of Unfair Business Practices (B&P §17200);** **2. Strict Products Liability, Warning Defect;** **3. Negligent Misrepresentation** **4. Loss of Consort** ***Jury Trial Demanded*** ***Related to: JCCP 4644 [Fosamax] Before Hon. Theirry Patrick Colaw, Orange County Superior Court***

Comes now Plaintiffs ELVIRA L. GORDON and BRIAN GORDON, who allege and complain as follows on information and belief, and who pray for relief from the court:

PARTIES

1. Plaintiffs ELVIRA L. GORDON and BRIAN GORDON (hereafter "Plaintiffs") are competent adults who resides in the State of California. Plaintiff ELVIRA L. GORDON (hereafter "PLAINTIFF Elvira") suffered an atypical femur fracture and related conditions caused by use of Fosamax, and generic Fosamax, designed, sold, marketed, and labeled by the defendants in this matter.

2. DEFENDANTS, DOES 1 to 50, and each of them are and were at all times relevant to this Complaint the manufacturers, distributers, furnishers, retailers, and/or marketers of, the Fosamax and generic Fosamax used by Plaintiff Elvira.

3. The names and capacity of defendants, and each of them, sued as DOES 1 through 50, inclusive, (hereafter "DOES" and included in references to "Defendants") are unknown to Plaintiffs at this time who, therefore, sue these defendants by such fictitious names. Plaintiffs are informed and believe, and thereon allege, that each of the defendants designated as a DOE is legally responsible for the events and happenings referred to in this Complaint, and directly caused injury and damages to Plaintiffs. Plaintiffs will amend this Complaint to reflect the true identities of DOE defendants upon their discovery.

4. Plaintiffs note that Fosamax appears to be manufactured, distributed, sold, and marketed by a network of companies and entities working as an enterprise, including Defendants, DOES 1 to 25, and each of them. Plaintiffs reserve the right to add additional defendants related to this enterprise as appropriate following discovery and disclosure. Plaintiffs also contend that the entire enterprise acts with joint enterprise, coordination, ratification, express approval, and mutual agency such that each Defendant and DOE is liable for the whole enterprise.

5. Defendants, DOES, and each of them, were at all times mentioned, the agents, representatives, employees, partners, of each of the other defendants and were at all times mentioned acting within the course and scope of said agency, representation, employment, partnership, joint venture or relationship stated therein, and were acting with the consent and knowledge of each of the other defendants.

JURISDICTION AND VENUE

6. The injuries and false statements giving rise to this litigation occurred in California.

7. Defendant OPTUMRX, INC. is a California Corporation with its principal place of business in California.

8. The damages asserted in this Complaint exceed the jurisdictional minimums of this Court

9. Defendants, DOES, and each of them market and sell their subject products in the jurisdictional area of this Court in high volume and with the expectation that they may be hailed into

court in this jurisdiction. Such minimum contacts for personal jurisdiction include but are not limited to the following:

a. Fosamax and its generics are and at all relevant times were available for sale in . California.

b. OPTUMRX, INC. is a California corporation.

c. NORTHSTAR RX LLC is a registered with the California Secretary of State, and maintains an office with managerial functions. including operations by its general counsel, in San Francisco, California. NORTHSTAR RX LLC sells and at all relevant times did sell Fosamax generics in California, including to Plaintiff.

d. MERCK & CO., INC obtained FDA approval to sell brand-name Fosamax. Its company name is on the official FDA drug facts sheet, and it has a duty under the law to keep the brand-name drug fact sheet current, and thereby assist in keeping. the generic drug fact sheets current. MERCK & CO., INC. operates through multiple related organizations, including but not limited to DOHME CORP., which ostensibly holds the copyright to the Fosamax drug sheet, as reflected on the drug sheet(s) as published at FDA.gov. Both these two companies are listed on the brand-name drug sheet as parties responsible for Fosamax and its labeling. MERCK SHARP & DOHME CORP. is registered wit the California Secretary of State. Both these two companies do business in California in the sale of Fosamax and related enterprises and intentionally inject the Fosamax and related generic products onto the market within California, and their officers and directors consciously understand that consumers in California have and will use these products.

GENERAL FACTUAL ALLEGATIONS

10. Defendants, DOES 1 to 50, and each of them, either directly or through agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment and prevention of osteoporosis, Paget's Disease, and other uses.

11. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX for several years, including PLAINTIFF, have suffered and may continue to suffer severe and permanent personal injuries, including. weakened or brittle bones, multiple stress fractures,

and low energy femoral fractures as a result of severely suppressed bone turnover caused by Fosamax.

12. Collectively and individually, Defendants, and DOES 1 to 50 concealed and continues to conceal its knowledge of FOSAMAX's luck of long term benefit and unreasonably dangerous risks from PLAINTIFF, her physicians, other consumers, and the medical community. Specifically, each such Defendant has yet to adequately inform consumers and the prescribing medical community about the well-established risks of long term FOSAMAX use including severely suppressed bone turnover and low energy femoral fractures.

13. As a result of each such Defendant's actions and inaction, PLAINTIFF was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiff's various injuries and damages. Plaintiff accordingly seeks compensatory damages, statutory damages, and punitive damages to the extent allowed under applicable law.

14. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by each such Defendant Merck as FOSAMAX or its generic.

15. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

16. There are two classes of bisphosphonates: the N containing (nitrogenous) and non N-containing (non nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: paxnidronate (Aredia); ibandronate (Boniva); risidronate (Actonel) and alendronate (FOSAMAX). The non nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid).

17. FOSAMAX works by inhibiting bone resorption and suppressing bone turnover. Bone mineralization occurs in two phases. Primary mineralization occurs while new bone is forming. Because FOSAMAX severely suppresses bone turnover, bone remodeling and primary mineralization are inhibited. Secondary mineralization of existing bone however, continues to occur. This results in an increase in the tissue mineral content of the bone, which translates to an increase in bone mineral density

(BMD). Increased BMD does not necessarily correspond to a reduction in the risk of fracture. In fact, through the bisphosphonate mechanism of action, with long-term use of bisphosphonates, bone becomes highly mineralized, homogenous, brittle, and more susceptible to fracture.

18. Prior to the introduction of FOSAMAX, the diagnosis of osteoporosis included clinical criteria such as prior bone fracture. 'Through the use of the 1990's advent of BMD based diagnosis for osteoporosis, the number of women diagnosed with osteoporosis skyrocketed. The BMD diagnostic criteria for osteoporosis has not been proven to correspond to those women who are most at risk for fracture. In fact, as of recently, due to the widespread over prescription of anti osteoporosis medications, including FOSAMAX, the World Health Organization no longer recommends using the arbitrary standard deviation system for the BMD based diagnosis of osteoporosis. It instead developed an algorithm called FRAX to assess a person's risk of fracture and the need for medication. FRAX takes into account a number of clinical risk factors rather than just BMD alone.

19. As medical researchers have concluded: "The use of surrogate endpoints such as BMD to predict fracture reduction risk should be approached with caution, as the relationship between BMD changes . and fracture risk reduction with antiresorptive therapies [such as FOSAMAX] is uncertain." Marcus, R., et al., Anti Resorptive Treatment of Post Menopausal Osteoporosis: Comparison of Study Designs and Outcomes in Large Clinical Trials with Fracture as an Endpoint, 23 Endocrine Rvws. 1637 (2002).

20. Numerous studies have confirmed that the effects of FOSAMAX on bone continue for years after treatment is discontinued. One studied showed that bone turnover was still inhibited by more than 50% 5 years after the discontinuation of FOSAMAX therapy. Strewler, G., Decimal Point Osteoporosis at the 10 Year Mark, 350 N. Engl. 1. Med. 1172 (2004). Merck's own studies reveal that FOSAMAX has a half life in bone of greater than ten years.

21. Each such Defendant knew or should have known that by inhibiting bone turnover while at the same time allowing the secondary mineralization of old bone to continue, long term FOSAMAX therapy would result in bones becoming highly mineralized, brittle and more susceptible to fracture. This is especially true given the fact that the effects of FOSAMAX on the bone accumulate and continue for years after treatment is discontinued.

22. Each such Defendant failed to conduct adequate and sufficient post marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

23. Each such Defendant promoted Fosamax as an effective treatment for osteoporosis that significantly reduced the risk of fracture in post menopausal women.

24. Each such Defendant's 1997 Fracture Intervention Trial (FIT) reported a 47% reduction in the risk of new vertebral fractures and a 28% reduction in the risk of clinical fractures in postmenopausal women taking alendronate compared to those taking a placebo. Ensrud et al., Treatment with Alendronate Prevents Fractures in Women with Highest Risk, 157 Arch. of Int. Med. 2617 (Dec. 8/22,1997).

25. Medical researchers in the January 19, 2008, issue of the British Medical Journal revealed that the manner in which the data on the degree to which bisphosphonates such as FOSAMAX reduce the risks of fracture is presented tends to exaggerate the actual fracture reduction benefit conferred. According to the authors, published clinical trials exaggerated the fracture reduction benefits by reporting results in terms of relative risk, rather than absolute risk. As the authors state: "Impressive sounding reductions in relative risk can mask much smaller reductions in absolute risk." By expressing fracture risk reduction in terms of "relative risk" rather than "absolute risk", the purported benefits of the drugs appear larger than they actually are in the general population. As a result, billions of dollars are being spent on a drug that has questionable utility for the ultimate goal of fracture reduction.

26. Correspondingly, when examined in a clinical setting, later observational studies revealed that when compared to a clinical setting, the FIT study exaggerated the benefit derived from alendronate therapy in reducing the risk of fracture. The 2006 ICARO study concluded that the incidence of fractures during treatment with antiresorptive agents, including FOSAMAX, in a clinical setting is considerably higher than that observed in randomized clinical trials, especially when therapy was not supplemented with calcium and vitamin D. Silvano et al., Fracture Incidence and Characterization in Patients on Osteoporosis Treatment: The ICARO Study, 21 J. Bone and Mineral Research 1565 (2006).

27. Long term studies of the effects of FOSAMAX therapy revealed that the benefit of remaining on Fosamax for longer than 5 years was also limited. One study, known as the FLEX study, concluded that while women who discontinued FOSAMAX after 5 years of therapy experienced a

moderate decline in BMD, their BMD remained above baseline and they did not experience a significant increase in the number of actual fractures when compared to women who continued FOSAMAX therapy for more than 5 years. Black et al., Effects of Continuing or Stopping Alendronate After 5 Years of Treatment, 296 JAMA 2927 (2006). The results of this study suggested that continuing FOSAMAX therapy for more than 5 years likely does not benefit the majority of women taking the drug. It was also observed in this study that during the later years of the study, the non vertebral fracture rate of women on alendronate appeared to be the same or higher as during the first three years of alendronate therapy, despite higher bone mineral density levels.

28. Each such defendant, including but not limited to Merck, has been aware of sound scientific and medical evidence that safer alternative therapies, such as vitamin D and calcium supplements, effectively reduce the risk of non vertebral fractures without the harmful side effects that can result from long term FOSAMAX use. For example, results of a three year study of the effect of calcium and vitamin D supplementation on bone density showed that women taking calcium and vitamin D supplements had significantly less total body bone loss and substantially fewer fractures compared to women in the placebo group. Hughes et al., Effects of Calcium and Vitamin D Supplementation on Bone Density in Men and Women 65 Years of Age or Older, 337 N. Engl. J. Med. 670 (1997). The degree of fracture reduction with calcium and vitamin D closely follows the results and degree of benefit presented in Merck's studies of alendronate.

29. Despite evidence of the positive effects of vitamin D and calcium on bone health and fracture risk, along with evidence of FOSAMAX's reduced efficacy when not supplemented with vitamin D and calcium, each such Defendant has never done a head to head comparative study of treatment with FOSAMAX alone versus treatment with vitamin D and calcium alone .

30. There is also evidence from at least one animal study that the severe suppression of bone turnover and bone remodeling that occurs with alendronate therapy, can result in the accumulation of microdamage in bone as well as a reduction in some of the biomechanical properties of bone. Mashiba et al., Suppressed Bone Turnover by Biophosphonates Increases Microdamage Accumulation and Reduces Some Biomechanical Properties in Dog Rib, 15 J. Bone and Mineral Research 613 (2000).

31. These findings were further reflected in human studies: "Our findings raise the possibility

that severe suppression of bone turnover may develop during long term alendronate therapy, resulting in increased susceptibility to, and delayed healing of, nonspinal fractures." Odvina, Clarita V., et aI., Severely Suppressed Bone Turnover: A Potential Complication of Alendronate Therapy, 90 J. Clin. Endocrinol. Metab. 1294 1301 (2005).

32. On January 7, 2008, the FDA issued a medical advisory, warning doctors and FOSAMAX patients of the "possibility of severe and sometimes incapacitating bone, joint, and/or muscle pain," and advising physicians to discontinue prescribing FOSAMAX if such complaints occurred during therapy. One week later, an article in the January 15,2008 edition of the Journal of Rheumatology concluded that FOSAMAX patients have a 287% higher chance of suffering aseptic osteonecrosis (at a non-specified site) than those not taking the drug.

33. Over the last few years, there have been an increasing number of reports of patients suffering multiple stress fractures and low energy femoral fractures as a result of severely suppressed bone turnover caused by long term FOSAMAX use. Severely suppressed bone turnover from long term FOSAMAX use has been well recognized in the medical literature.

34. Despite its knowledge of this dangerous side effect than can result from long term FOSAMAX use, each such Defendant refuses to warn patients, physicians and the medical community about the risk of severely suppressed bone turnover. Each such Defendant continues to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.

35. Rather than evaluating and verifying the safety of long term FOSAMAX use with respect to bone strength and stress fractures, each such Defendant proposed further uses of FOSAMAX, such as FOSAMAX D, and sought to extend the exclusivity period of FOSAMAX through 2018.

36. FOSAMAX was one of each such Defendant's top selling drugs, averaging more than $3 billion a year in sales before it lost patent exclusivity and a generic version became available in 2008.

37. Consumers, including PLAINTIFF, who have used FOSAMAX for the treatment or prevention of osteoporosis, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with long term FOSAMAX therapy.

38. As a direct result, PLAINTIFF was prescribed FOSAMAX for the treatment and/or

prevention of osteoporosis and has been permanently and severely injured, having suffered serious consequences from long term FOSAMAX use.

39. The FOSAMAX manufactured and sold by each such Defendant was expected to reach and did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold.

40. Plaintiff was prescribed and used FOSAMAX for the treatment or prevention of osteoporosis and/or osteopenia. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by each such Defendant.

41. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, even when used as intended or in a reasonably foreseeable manner.

42. As a direct and proximate result of her long term FOSAMAX use, Plaintiff suffered severely suppressed bone turnover and sustained bi-lateral femur fractures.

43. As a direct and proximate result of long term FOSAMAX use, Plaintiff suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress, including the mental anguish Plaintiff suffers due to her knowledge that she will have life-long impairment and complications as a result of the injuries she sustained from her use of FOSAMAX.

44. Plaintiff would not have used and her physician would never have prescribed FOSAMAX for so many years had each such Defendant properly disclosed the risks associated with long term FOSAMAX use. Plaintiff took FOSAMAX from approximately July 2011 to May 2017. On May 27, 2017, she suffered a fracture of her right femur. She did not discover that FOSAMAX was possibly considered a defective product until after August of 2019.

45. Each such Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with long term FOSAMAX use. The running of any applicable statute of limitations has been tolled by reason of each such Defendant's fraudulent concealment.

46. As a result of each such Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, which were the direct and proximate

result of Defendant's acts, omissions, and misrepresentations.

47. Plaintiff was provided Fosamax and its generic by Defendants, DOES 1 to 50, and each of them, including but not limited to OPTUMRX.

48. Plaintiff was first furnished with Fosamax in or about 2007.

49. From the time period of 2007-2011, neither Fosamax nor its generic included any warning of atypical fracture, even though Defendants, DOES 1 to 50, and each of them knew or should have known of this and related dangers of use.

50. After January of 2011, neither Fosamax nor its generic included sufficient warnings concerning atypical fractures, even though Defendants, DOES 1 to 50, and each of them knew or should have known that the warning was insufficient in that it failed to appropriately advise patients or their care givers of the risks of Fosarnax use, including the actual danger and degree of risk of danger associated with Fosarnax use. This includes but is not limited to using minimizing language to downplay the risk such that an ordinary patient and ordinary physician would not appreciate the degree of risk associated with Fosarnax use. The warning, even when placed in 2011, would lead a reasonable physician and patient to believe there was only a trivial risk of atypical fracture, that such a condition would be heralded by advance notice through leg pain or other warning symptom, and that the risk of use was far outweighed by the potential benefits, and did so result with respect to Plaintiff and her prescribing care provider(s).

51. Had Defendants, DOES 1 to 50, and each of them appropriately provided adequate warnings, Plaintiffs physician, and Plaintiff, would have taken steps to discontinue Plaintiff's Fosarnax use or take other mitigating measures.

52. FDA and other regulatory bodies would not have precluded Defendants, DOES 1 to 50, and each of them from adopting such appropriate and adequate warnings.

53. OPTUMRX provided Plaintiff with the subject medication. In so acting, OPTUMRX ostensibly acted as a mail-order pharmacy. As a pharmacy in California, OPTUMRX was subject to all rules and regulations of practice within this state, including such rules and regulations requiring oral advisement of patients and proper consultation of patients, including but not limited to 16 CCR § 1707.2, which required OPTUMRX to give " oral" warnings for use to Plaintiff when the label change

was made in January of 2011, and as appropriate with other developments.

54. OPTUMRX has never provided Plaintiff with an oral' consultation, and instead functions as a mail-order delivery service that merely distributes drugs rather than providing a proper service as a pharmacy.

55. Such behavior by OPTUMRX is part of an ongoing and longstanding business practice that is unfair and unlawful. It is unlawful because, among other things, it violates 16 CCR § 1707.2. It is unfair because, among other things, it exposes patients such as Plaintiff to risk by eliminating the protective and consulting aspect of licensed pharmacy services.

56. OPTUMRX received money as a result of this practice, including but not limited to money from Plaintiff for purchase of Fosamax that she would not have purchased had appropriate consultation been provided by OPTUMRX. Plaintiff suffered pecuniary loss as a result of such purchases, as well as physical injury and attendant damages that resulted from the use of Fosamax which would not have occurred had OPTUMRX provided her with a consult. She is one of many similarly situated patients who have suffered complication as a result of OPTUMRX' s business policy of not providing oral consults in accordance with rules and regulations such as those cited herein.

57. This practice by OPTUMRX is ongoing and continues to harm similarly situated ?consumers.

FIRST CAUSE OF ACTION:
VIOLATION OF BUSINESS AND PROFESSIONS CODE § 17200
BY PLAINTIFF AGAINST OPTUMRX AND DOES 1 to 2

58. All prior paragraphs are incorporated by reference as though stated fully here.

59. OPTUMRX, DOES 1 to 2,. and each of them operate a business in California which sells prescription drugs to consumers. In one sense, the business is a pharmacy. However, the business does not engage in the ordinary practice of consulting patients/consumers about the medications provided, Plaintiff, despite her years-long use of OPTUMRX services to obtain Fosamax was never provided with any oral consultation about this or any other medication, despite such oral consultation being required by law, including but not limited to as outlined herein. This is a general business practice of OPTUMRX, DOES I to 2, and each of them.

60. In so acting, OPTUMRX, DOES 1 to 2, and each of them engage in an unlawful and

unfair practice as outlined herein. This practice violates California Business and Professions Code § 17200.

61. OPTUMRX, DOES 1 to 2, and each of them earn profits as a result of such behavior, including but not limited to the profits obtained by sales to Plaintiff as outlined herein.

62. OPTUMRX, DOES 1 to 2 and each of them caused Plaintiff actual injury, damages, and pecuniary loss as outlined herein, including but not limited to: continued sales of Fosarnax, which Plaintiff would not have made if provided with an appropriate consultation; physical injury from Fosamax use as outlined herein; associated medical. bills and economic damages resulting from the use of Fosamax which would not have occurred if Plaintiff was provided with an appropriate consultation.

63. Plaintiff seeks equitable relief including return of her money paid for Fosamax, and an injunction compelling OPTUMRX, DOES 1 to 2, and each of them to bring their business operations into compliance with the law with respect to consultations and operation of a pharmacy such that the mail-order nature of the business does not continue to subject patients to inadequate protections and increased risk of harm.

64. Plaintiff seeks an award of attorney fees and costs to the degree such an injunction confers a benefit on the public.

65. This cause of action is pled in the alternative with respect to whether OPTUMRX, DOES 1 to 2, and each of them operate as a pharmacy or as a distributor subject to strict products liability. To the degree that OPTUMRX, DOES 1 to 2, and each of them do not operate as a pharmacy, their conduct is misleading to consumers and doctors, and represents the unlawful and unlicensed practice of pharmacy, also giving rise to this 17200 claim, as well as the other claims herein.

SECOND CAUSE OF ACTION:
STRICT PRODUCTS LIABILITY - WARNING DEFECT BY PLAINTIFF AGAINST ALL DEFENDANTS

66. All prior paragraphs are incorporated by reference as though stated fully here.

67. DEFENDANTS, DOES, and each of them, manufactured, distributed, and sold the subject product (Fosamax and/or its generics), and were responsible for its labeling and warnings.

68. DEFENDANTS DOES 1-50, and each of them at all relevant times were responsible,

pursuant to FDA regulation, for promulgating the label and related communications for all Fosamax and related generics, such that the information provided to medical providers and Plaintiff ultimately came from these parties. They therefore had a duty consumers and medical providers, including PLAINTIFF and the other defendants, to include appropriate warnings including those educating about the actual risks associated with use of the drug. In this way, these defendants had so-called innovaor duties and liability pursuant to California tort law, which included duties of providing adequate warnings to PLAINTIFF and the other defendants and physicians relating to the drug and related generics.

69. The subject product had potential risks and side effects as alleged herein that were actually known and in the alternative were knowable by Defendants, DOES, and each of them. Such knowledge existed in the medical literature as alleged, and on information and belief was ascertainable from data collected by Defendants, DOES, and each of them during drug development, drug approval, post release, and marketing data, among other sources.

70. Such potential risks, including that of atypical fractures of the femur as alleged herein, presented a substantial danger when the product was used or misused in an intended or foreseeable way, especially with respect to continuous use.

71. Ordinary consumers, including PLAINTIFF, would not have recognized such risks and side effects. Neither would the reasonable prescribing physician.

72. DEFENDANTS, DOES, and each of them, failed to appropriately warn PLAINTIFF'S prescribing health care providers about such potential risks land side effects, and failed to meet their continuing duty to warn physicians as long as the product was in use.

73. DEFENDANTS, DOES, and each of them, failed to adequately warn or instruct of such risks and side effects.

74. As a direct and proximate result of the lack of sufficient instructions or warnings as alleged herein, PLAINTIFF was injured and suffered attendant damages.

THIRD CAUSE OF ACTION:
NEGLIGENT MISREPRESENTATION BY PLAINTIFF AGAINST ALL DEFENDANTS

75. All prior paragraphs are incorporated by reference as though stated fully here.

76. Defendants, DOES, and each of them represented to Plaintiff and her care providers that it was safe to use Fosamax or its generic on a continuous basis without disclosing in plain and understandable terms the risk of atypical femur fracture as could be reasonably appreciated and understood by the patient and her care providers. The gist of the communications regarding risk from Defendants, DOES, and each of them prior to January 2011 was that no such risk existed despite their knowing that such a risk did exist and that it was not trivial and would, if fully known and understood, lead some patients and care providers such as Plaintiff's to select other treatment modalities. The gist of the communications thereafter was that there was no practical risk, but that there was merely an academic risk that should not affect treatment modality selection absent ongoing pain symptoms. Defendant,; DOES, and each of them knew or should have known that such communication after 2011 was misleading and could confuse care providers and patients,

77. Such representations were not true. These include but are not limited to each iteration of the drug label, drug fact sheet, drug inserts, and marketing and informational material sent to or otherwise made available physicians, as well as market-wide marketing directed towards patients/consumers, and also as to industry/defendant-funded research articles, editorials, publications, and continuing medical education and seminar materials.

78. Without respect to whether Defendants, DOES, and each of them may have honestly believed that such representations were true, there was no reasonable grounds for them to believe such representations were true when they made it. Instead, given the available medical information referenced herein and the duties of care referenced herein, Defendants, DOES, and each of them had every reasonable ground and obligation to believe and treat such beliefs/representations as false. Alternatively, Defendants, DOES, and each of them knew the representations were false, or were in making the representations.

79. Defendants, DOES, and each of them intended that Plaintiff and her health care providers rely on these representations, and they reasonably did so.

80. As a direct and proximate result PLAINTIFFS were injured and suffered attendant damages as discussed herein.

FOURTH CAUSE OF ACTION
(Against All Defendants Herein For Loss of Consortium)

81. The plaintiffs incorporate herein by reference each and every allegation contained in paragraphs 1 through 80 of this Complaint.

14. Plaintiff Brian Gordon was the lawful spouse of plaintiff Elvira L. Gordon at all times herein and, as a result of the acts of defendants, and as a result of plaintiff's injuries, plaintiff's husband, Brian Gordon, has suffered the loss of love, affection, comfort, society, support, services and consortium, all to his general monetary damage.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray judgment against Defendants, DOES 1 to 25, and each of them, as hereinafter follows:

1. As to the first cause of action:

   a. Restitution

   b. Injunction as discussed herein, including but not limited to an order to institute corporate procedures to provide appropriate oral consults or stop subject defendants from holding themselves out as pharmacies in California

   c. Attorney fees

2. As to the second and third causes of action:

   a. For non-economic damages according to proof

   b. For economic damages according to proof

   c. Plaintiff reserves the right to amend to seek punitive damages according to proof in the event that the misrepresentations herein are evidenced to he intentional, wanton, or reckless in nature.

3. As to all causes of action:

   a. For costs of suit

   b. For prejudgment and post judgment interest as allowed by law

   c. For all other relief as the court may deem appropriate

For the purposes of due process and default judgment regarding claims not characterized as personal injury, Plaintiffs set forth a prayer of not more than $3,000,000 (Three Million US Dollars) understanding this amount be arrived at purely for reservation of rights for these purposes and is subject to change, including increase, during litigation of this matter.

DATED: May 28, 2020

WALKER, HAMILTON & KOENIG, LLP

By: _____
Timothy M. Hamilton
Attorneys for Plaintiffs